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PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract will provide the procurement of bulk chemicals and drugs that are needed by the Drug Treatment Programs (DTP) for preclinical and clinical use. The compounds could be known or new chemicals with a wide variety of chemical structures. Multi-step preparation sequences will generally be involved and process development for scale up preparation will be expected using provided investigator's procedures. The quantity of a given material synthesized may range from multi-grams to multi-kilograms. All materials prepared will be fully characterized for high purity and the preparative cost will also be calculated. Most of assigned projects should be performed under the current good manufacturing practice (c-GMP). Thus, the contractors must be a FDA approved bulk manufacturer.

ARTICLE B.2. ESTIMATED COST - OPTION

- The estimated cost of the Base Period of this contract is \$_____.
- The fixed fee for the Base Period of this contract is \$_____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.
- The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is \$_____.
- If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost (\$)	Fixed Fee (\$)	Estimated Cost Plus Fixed Fee (\$)
Base Period: (04/01/2012 - 03/31/2013)			
Option Period 1: (04/01/2013 - 03/31/2014)			
Option Period 2: (04/01/2014 - 03/31/2015)			
Option Period 3: (04/01/2015 - 03/31/2016)			
Option Period 4: (04/01/2016 - 03/31/2017)			

	Estimated Cost (\$)	Fixed Fee (\$)	Estimated Cost Plus Fixed Fee (\$)
Total [Base Period and Option(s)]			

ARTICLE B.3. ESTIMATED COST - INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71 (June 2010)

- a. The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is \$_____.
- b. The following represents the schedule* by which the Government expects to allot funds to this contract:

CLIN, Task, Number, or Description	Start Date of Period or Increment of Performance	End Date of Period or Increment of Performance	Estimated Cost (\$)	Fee (\$) (as appropriate)	Estimated Cost Plus Fee (\$) (as appropriate)
			[Total]	[Total]	[Total]

*To be inserted after negotiation

- c. Total funds currently obligated and available for payment under this contract are \$_____ .
- d. The Contracting Officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs b. and/or c., above.
- e. Until this contract is fully funded, the requirements of the clause at FAR 52.232-22, Limitation of Funds, shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232-20, Limitation of Cost, shall govern.

(End of Clause)

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

1. Pre-Award Site Visit

a. Pre-award site visits may be conducted to aid in the selection of the most qualified offeror. A pre-award site visit may include:

- (1) examining the offeror's facilities to ensure that they are adequate;
- (2) ascertaining potential management support;
- (3) reviewing proposed key personnel;
- (4) assessing the ability of the offeror and their personnel pertaining to the project;
- (5) complete negotiations concerning the offeror's proposal

b. The pre-award site visit will be made promptly after the establishment of the competitive range. All offerors in the competitive range may not require a site visit.

c. The pre-award site visit team will include the Project Officer (PO), Contracting Officer/Contract Specialist (CO/CS), the Technical Evaluation Panel or a portion thereof, and if necessary, other personnel selected by the Chairperson of the Technical Evaluation Panel for particular expertise.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated November 1, 2011, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]*

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) 1 hard copies of these reports will be required as follows if the document is more than 100 pages in length:

- Monthly
- Quarterly
- Semi-Annually
- Annually
- Annually (with a requirement for a Draft Annual Report)
- Final - Upon final completion of the contract
- Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

1) **Monthly Progress Reports.**

The Contractor shall submit to the Project Officer a monthly progress report. This report shall include a brief description including synthetic schemes of each work assignment performed during the preceding month. This report shall also include total cost expended for each project during the reporting period and cumulative costs for each assignment. The cost data should correspond to the reporting period. The format of the cover sheet of the report should include name of contractor,

contractor number, date prepared, work assignment number, NSC number, compound name, quantity assigned, date assigned, estimated target date for completion, and project status. Data obtained only during the reporting period should be included.

2) Annual Progress Reports:

The Contractor shall submit a progress report once per year, which summarizes the results of work assignments for individual compounds over the entire reporting period. The report should include complete experimental data on the compounds that were worked on during the reporting period. Each report shall also contain, as the first section, a summary of the salient results obtained during the reporting period. An annual report will not be required for the period when the final report is due.

3) Final Reports:

The Contractor shall submit a final contract report that documents and summarizes the results obtained over the entire period of the contract. The report shall be in sufficient technical details to explain comprehensively the results achieved including the details of failed experiments. The final report shall be submitted on or before the last day of the contract period.

b. Other Reports/Deliverables

1) Final Work Assignment Reports:

The Contractor shall submit a final work assignment report to the Project Officer within 30 calendar days after the completion of the work assignment. The report should include detailed experimental procedure and spectral data for each intermediate and the final target compound. The report should also include a synthetic scheme, analytical methods performed, a certificate of analysis, a source list of raw materials, solvents and reagents used, and information on package material used for shipment of the bulk material. For assignments for a compound previously prepared, the report should refer to the report previously submitted unless additional or revised new information are obtained during the performance of the repeated assignments.

The following format for the reports should be followed:

Part 1 includes total cost for the project and general statements concerning history of the project and any miscellaneous discussions.

Part 2 includes technical information only such as synthetic scheme, detailed experimental description, spectral data for each intermediate and the final target compound, a source list of raw materials, solvents and reagents used, and information on packaging materials. A format of the experimental description should be similar to that used in the publication journals (e.g. J. Med. Chem.).

Part 3 includes analytical methods performed, analytical spectra, and data sheet.

The part 1, 2 and 3 should be a stand-alone document.

2) Additional Reports:

The Contractor also shall submit in a timely manner other technical or summary reports which may be requested by the Project Officer.

a) Special Business Reports:

Approximately ninety (90) days prior to the expiration of each funded phase, the Contractor shall prepare and furnish to the Contracting Officer an updated detailed estimate of projected expenditures for the subsequent phase. Such estimates shall follow the same itemized format as the basic proposal submitted hereunder, and will

serve as a basis for additional allocation of funds under this contract, pursuant to the General Provisions thereof, entitled "Limitation of Funds."

Interim reports on projects of high interest or on particular problems encountered in the course of the work may be required by mutual agreement of the Contractor and the Project Officer or the designated representative of the Project Officer.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer / Heidi A Crawley
National Institutes of Health
National Cancer Institute
Office of Acquisition
8490 Progress Drive
Suite 400, Room 4037
Frederick, MD 21701- ___

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (<http://www.iedison.gov>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. SHIPPING

A Material Safety Data Sheet is required in shipments. Additionally:

Prepared or acquired bulk drugs/chemicals should be packaged and labeled according to industry best practices and delivered to the NCI Repository or to a place where the Project Officer indicates. The current address for the repository is as follows:

Project Officer (To be determined)
c/o Fisher BioServices Corp.
NCI-Chemotherapeutic Agents Repository
1592 Rockville Pike, Suite E
Rockville, MD 20852

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Project Officer/COR is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
TBA (Project Officer)
6130 Executive Blvd.
Executive Plaza North, Room 8054
Rockville, MD 20852

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from April 1, 2012 through March 31, 2013.
- b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
Option 1	April 1, 2013 through March 31, 2014
Option 2	April 1, 2014 through March 31, 2015
Option 3	April 1, 2015 through March 31, 2016
Option 4	April 1, 2016 through March 31, 2017

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

b.

Item	Report	Period Covered	Due Date	Copies to the Contracting Officer	Copies to the COR
(1)	Monthly Progress	Each month	10th day of each month	One (1) PDF format copy	(1) PDF Format copy
(2)	Annual Progress	Each year	yearly	One (1) PDF format copy	(1) PDF Format copy
(3)	Final Work Assignment	varies	30 calendar days after completion of the work assignment	One (1) PDF format copy	(1) PDF Format copy
(4)	Additional	varies	Upon request	0	(1) PDF Format copy
(5)	Special Business (annual financial projection)	Yearly	90 days prior to the expiration of each funded phase	One (1) PDF format copy	(1) PDF Format copy
(6)	Interim	varies	Upon request	0	(1) PDF Format copy
(7)	Final	Entire contract period	Before or on the last day of the contract	One (1) PDF format copy	(1) PDF Format copy

- c. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No	Quantity
Contracting Officer	1,2,3,5,7	One (1) electronic copy unless over 100 pages- in which case one (1) hard copy is required.
COR	1,2,3,4,5,6,7	One (1) electronic copy

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR)

The following Contracting Officer's Technical Representative (COTR) will represent the Government for the purpose of this contract:

TBD

The COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

[The alternate COTR is responsible for carrying out the duties of the COTR only in the event that the COTR can no longer perform his/her duties as assigned.]

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

[The Contracting Officer hereby delegates the COTR as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.]

The Government may unilaterally change its COTR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
To be specified prior to time of award	Principal Investigator
To be specified prior to time of award	Assistant Principal Investigator

ARTICLE G.3. WORK ASSIGNMENT PROCEDURES

In providing support under this contract, the Contractor shall initiate work only when so directed by a Work Assignment (Attachment provided in SECTION J). Approval of a Work Assignment shall **not** constitute approval to exceed any item listed in the contract or general clauses of the contract. Work Assignment amounts shall not exceed the total amounts listed in the contract (time, dollars, effort, consultants, travel, etc.). The Contracting Officer's Technical Representative (COTR) with Contracting Officer approval, is authorized to initiate Work Assignments and to sign Work Assignments indicating satisfactory performance/delivery of the services/product required in each Work Assignment. The Contractor shall assure, prior to commencing work on any Work Assignment, that written approval of the COTR and the Contracting Officer has been obtained. A Work Assignment which does not contain both Contracting Officer and COTR approval signatures shall be considered invalid and costs incurred for such work shall be considered unallowable. The Contractor shall not exceed the estimated labor hours, estimated Work Assignment amount, or change the Work Assignment leader without prior written approval of the COTR and the Contracting Officer by modification of the Work Assignment. The day-to-day operational and administrative details of

the Work Assignment system will be established by the COTR with input from the Contractor. The Work Assignment system will operate within the following general guidelines:

a. Work Assignment (W.A.) Information

1. All work to be assigned under this contract shall relate directly to one or more of the task areas listed in the Statement of Work.
2. Each W.A. shall be written for the conduct of a specific, finite task.
3. Each new W.A. shall be numbered serially beginning with 01.
4. Each W.A. shall be completed on the form entitled "Sample Contract Work Assignment" and listed as an Attachment in Section J of this contract.
5. Upon award of the contract, an Administrative Work Assignment as shown in SECTION J, Attachments, shall be issued on a yearly basis. This Work Assignment will cover the time and expenditures necessary for the administration of the contract.

b. Initiation of a W.A.

1. The COTR will initiate Part I of the W.A.
2. The Contractor shall complete Part II and obtain the appropriate signature. The Contractor shall forward the proposed W.A. to the COTR.
3. Upon receipt of the proposed W.A. and after determining that the proposed W.A. is acceptable, the COTR will sign Part II to indicate recommendation for approval and forward to the Contracting Officer.
4. Upon receipt, the Contracting Officer will review the proposed W.A.
 - a. If approved, the Contracting Officer will sign Part II to indicate approval and will forward the W.A. to the Contractor with a copy to the COTR.
 - b. If not approved, the Contracting Officer will notify the COTR, stating the reasons for disapproval.
5. After receipt of the approved W.A., the Contractor shall begin work. The period of performance shall never precede the Contracting Officer Approval date.

c. Modification to a W.A.

1. Each amendment to an existing Work Assignment shall contain the original W.A. number and shall designate a modification number. Modification numbers for each W.A. shall be serially numbered beginning with 01 (for example, Work Assignment 01, Modification No. 01).
2. Each W.A. modification shall set forth in specific detail which portion(s) of the W.A. is to be modified.

d. Conclusion of a W.A.

1. For each W.A. performed, the Contractor shall prepare PART III of the Work Assignment for submission to the Contracting Officer.
2. This PART III submission shall include all actual information (cost, effort, and deliverables) relative to the W.A.
3. PART III of the W.A. shall be submitted as soon as possible and not to exceed three months after the closing date of the W.A. For those Work Assignments which expire within three months prior to the contract expiration date, PART III of the Work Assignment shall be submitted on the final contract day.
4. After verification that all work is complete and deliverables have been received and accepted, the COTR will sign Part III of the W.A. to indicate recommendation for approval and forward the W.A. to the Contracting Officer.

5. After verification that the W.A. has been satisfactorily completed, the Contracting Officer will approve completion of the W.A. by signing Part III of the W.A. and forward to the Contractor.

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

- a. The original invoice shall be submitted to the following **designated billing office**:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

- b. One copy of the invoice shall be submitted to the following **approving official**:

Heidi Crawley, Contracting Officer
Office of Acquisitions
National Cancer Institute, NIH
8490 Progress Dr., Suite 400 Room 4037
_____ MSC ____
Frederick, MD 21701- ____

E-Mail:crawleyha@mail.nih.gov

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:
 - a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute .
 - b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch C - ncibranchcinvoices@mail.nih.gov .
 - c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A*

VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

- d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [*Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- e. Invoice Matching Option. This contract requires a two-way match.
- f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

ARTICLE G.5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663
BETHESDA MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at:

http://rcb.cancer.gov/rcb-internet/reference/Appendix Q_HHS Contracting Guide.pdf.

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared on _____ [Insert Dates].

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

<http://www.cpars.csd.disa.mil>

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by the local public health or local law enforcement authorities to be inappropriate for such distribution.

ARTICLE H.3. PRESS RELEASES

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.4. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

ARTICLE H.5. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

The Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

ARTICLE H.6. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.7. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant

to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ARTICLE B.2., ESTIMATED COST PLUS FIXED FEE.

ARTICLE H.8. INFORMATION AND PHYSICAL ACCESS SECURITY

A. Additional NIH Requirements

1. SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)

a. Information Type:

Administrative, Management and Support Information:

Mission Based Information:

b. Security Categories and Levels:

Confidentiality Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Overall Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High

c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

ARTICLE H.9. CONFIDENTIALITY OF INFORMATION

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

A. In accordance with HHSAR Clause 352.224-70 'Confidentiality of Information' certain data provided to the Contractor under this contract shall be treated confidentially. The data to be treated confidentially is associated with certain 'discreet' compounds which are not available to the public because, for example, the owner may be in the process of obtaining a patent or the compound may be protected by a patent. Confidential information includes, but is not limited to, the identity of suppliers, compound structures, amounts being prepared, etc. When compounds are assigned to the Contractor for synthesis or purity evaluations, these discreet compounds will be identified by the letter 'D' as a prefix to the NSC number of the compound.

B. The Contractor will have access to proprietary information on compounds assigned by the NCI for re-synthesis, and the Contractor shall be required to treat all information obtained under this contract as strictly confidential. The Government will provide the Contractor with guidelines governing this requirement. All information supplied by the NCI or generated by the Contractor under this contract will be treated as strictly confidential and solely as Government property.

ARTICLE H.10. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. TBA"

ARTICLE H.11. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
 Department of Health and Human Services
 TIPS HOTLINE
 P.O. Box 23489
 Washington, D.C. 20026

ARTICLE H.12. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. Service Involving the Use of Information Technology YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from,

into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

ARTICLE H.13. INTELLECTUAL PROPERTY OPTION TO COLLABORATOR

NCI may collaborate with an outside investigator who has proprietary rights to compounds which may be assigned under this contract. This collaborator will be identified by the Contracting Officer's Technical Representative (COTR) at the time of assignment and in this case, the following option regarding Intellectual Property Rights will be applicable.

Contractor agrees to promptly notify the NCI and "Collaborator" in writing of any inventions, discoveries or innovations made by the Contractor's principal investigator or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using Collaborator's Study Agent (hereinafter "Contractor Inventions").

Contractor agrees to grant to Collaborator: (1) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (2) a time-limited first option to negotiate an exclusive world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Contractor Inventions on terms to be negotiated in good faith by Collaborator and Contractor. Collaborator shall notify Contractor, in writing, of its interest in obtaining an exclusive license to any Contractor Invention within six (6) months of Collaborator's receipt of notice of such Contractor Invention(s). In the event that Collaborator fails to so notify Contractor or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Contractor Invention, and Contractor will be free to dispose of its interests in such Contractor Invention in accordance with its own policies. If Contractor and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter, Contractor shall not offer to license the Contractor Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

Contractor agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 U.S.C. 201(e),* arising out of any unauthorized use of the Collaborator's Study Agent shall be the property of the Collaborator (hereinafter "Collaborator Inventions"). Contractor will promptly notify the Collaborator in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Contractor will cause to be assigned to Collaborator all right, title and interest in an to any such Collaborator Inventions and provide Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Contractor may also be conducting other more basic research using Study Agent under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA, and not to this clause.

*35 U.S.C. 201(e): The term "subject invention" means any invention of the Contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d)(FOOTNOTE 1) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

Protection of Proprietary Data

Data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the NCI and the Collaborator. The Contractor retains the right to publish research results subject to the terms of this contract.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp>

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. FAR Clauses **52.219-9, Small Business Subcontracting Plan** (January 2011), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.
- b. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

"(a) The Government may extend the term of this contract by written notice to the Contractor anytime within the contract period of performance provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension."

"c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 60 MONTHS."

2. FAR Clause **52.219-6, Notice of Total Small Business Set-Aside** (Nov 2011).

3. FAR Clause **52.219-14, Limitations on Subcontracting** (Nov 2011).

4. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (April 2009).

5. FAR Clause **52.222-4, Contract Work Hours and Safety Standards Act - Overtime Compensation - General** (July 2005).

6. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).

7. FAR Clause **52.227-14, Rights in Data - General** (December 2007).

8. FAR Clause **52.237-3, Continuity of Services** (January 1991).

9. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

HHSAR 352.223-71 Instruction to Offerors - Sustainable Acquisition

1. HHSAR 352.223-71 Instruction to Offerors - Sustainable Acquisition

Offerors must include a Sustainable Acquisition Plan in their technical proposals that describes their approach and the quality assurance mechanisms in place for applying FAR 23.1 - sustainable Acquisition Policy (and other Federal laws, regulations and Executive orders governing green purchasing) to this acquisition.

Note: if no sustainable acquisition possibilities exist please state the reasons why in a separately tabbed section of the technical proposal titled Sustainable Acquisition Plan.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (Non R & D)	N02CM17029-73 RFP Attachment 1 PackagingProposals.pdf
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp
Attachment 3:	Statement of Work	N02CM17029-73 RFP Attachment 3 SOW.pdf

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 4:	Technical Proposal Cost Summary	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 5:	Summary of Related Activities	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 6:	Proposal Summary and Data Record, NIH-2043	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 7:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 8:	Offeror's Points of Contact	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 9:	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 10:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 11:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 12:	Government Property Schedule	To be determined during negotiations. N02CM17029-73 RFP Attachment GFP.pdf
Attachment 13:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **Online Representations and Certifications Application (ORCA)** at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and
2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL: SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS** which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. QUESTIONS

a. Questions in response to this solicitation

The offeror may submit WRITTEN questions requesting clarification of the RFP contents. Information provided with each question must include the document name, specific page, paragraph, clause or other definitive citation requiring clarification. All questions must be submitted ELECTRONICALLY to Heidi Crawley at crawleyha@mail.nih.gov. FACSIMILE, TELEPHONE OR MAILED QUESTIONS WILL NOT BE ACCEPTED.

NOTE 1: It is respectfully requested that all questions be received by 12/27/2011 at 2:00 P.M., Eastern Prevailing Time to allow NCI adequate time to prepare and issue a response prior to the receipt of proposals. NCI will continue to accept questions up to the closing date and time for the RFP. HOWEVER, time may not permit responses to questions received after 12/27/2011 to be prepared and issued prior to the receipt of proposal(s).

NOTE 2: ALL proposals submitted in response to this RFP shall have each page numbered sequentially in order to facilitate the review process. Attachments and exhibits may be excluded, provided a title appears on each submitted attachment of exhibit. It is highly desirable that each page reference the Offeror's name or other identifier in the header or footer.

b. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2006)]

(a) *Definitions.* As used in this provision--

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.*

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before

award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
- (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
- (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.*

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (*insert page numbers, paragraph designations, etc. or other identification*)."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) *Contract award.*

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997).As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

c. NOTICE OF SMALL BUSINESS SET-ASIDE

1. **General.** Offerors are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.
2. **Definitions.** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the size standards in this solicitation. In addition to meeting these criteria, a small business concern submitting an offer in his own name shall furnish, in the performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas, provided that this additional requirement does not apply in connection with construction or service contracts.

d. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541990.
2. The small business size standard is 500.

e. TYPE OF CONTRACT AND NUMBER OF AWARDS

1. It is anticipated that [one/multiple award(s)] will be made from this solicitation and that the award(s) will be made on/about April 1, 2012.
2. It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Period of Performance of one base year and 4 1 year option periods, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

f. ESTIMATE OF EFFORT

It is expected that a non-R&D, multiple year, multiple award, work assignment, completion type contract with a one year base and four one year option periods will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort required to be approximately 9,375 hours per year. The estimate would be 5.0 full time equivalents (FTE) per year with completion and deliveries of the material targets of 10 to 15 assignments. A staff year is 1875 hours of direct labor per year excluding holidays and sick leaves. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

g. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

h. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

i. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

j. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer

Office of Acquisitions
National Cancer Institute
Riverside Five, Suite 400 Room 4037
8490 Progress Dr MSC ___
Frederick, MD 21701- ___

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

1. Contract Type and General Clauses

It is contemplated that a [cost-reimbursement [(completion/level of effort)/fixed price] type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

3. **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

4. **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. **Evaluation of Proposals**

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

7. **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

8. **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

9. Selection of Offerors

- a. The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -

1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

10. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 3 contracts completed during the past Two years and ALL CONTRACTS currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance

information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as \$500,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

11. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Data Universal Numbering System (DUNS) Number, FAR Provision 52.204-6 (April 2008).
- b. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).
- c. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- d. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain

your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

1. Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a. Statement of Work

1. Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

4. Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or

programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

1. Single Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

2. Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

3. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

4. Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

2. Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

4. Sustainable Acquisition Plan

4. Sustainable Acquisition

Offerors must include a Sustainable Acquisition Plan in their technical proposals that describes their approach and the quality assurance mechanisms in place for applying FAR 23.1 - sustainable Acquisition Policy (and other Federal laws, regulations and Executive orders governing green purchasing) to this acquisition.

1. DEFINITIONS:

A. Recycled Content Products

Recycled content products are products that are made from or contain recovered materials. That means replacing virgin materials with recycled materials, including post-consumer materials. There are currently more than 60 designated products in eight categories: paper and paper products, vehicular, construction, landscaping, park and recreation, transportation, non-paper office, and miscellaneous products. Examples of designated products include structural fiberboard, printing and writing papers. The current list of designated products, EPA's guidance, and related technical information can be found on EPA's web site at <http://www.epa.gov>.

B. Energy-Efficient Products: Energy Star®, FEMP-Designated, and Low Standby Power

EPAAct of 2005, Section 104 and FAR 23.203 require federal agencies to purchase Energy Star® qualified or Department of Energy's (DOE's) Federal Energy Management Program (FEMP)-designated products when procuring energy-consuming products.

The technical requirements that each product must meet to become Energy Star® qualified are available at ENERGY STAR Qualified Products : ENERGY STAR. Information on FEMP-designated products can be found at <http://www.eere.energy.gov/>. Information on low standby power products can be found on FEMP's web site at: <http://www.eere.energy.gov>.

C. Biobased Products

Biobased products are products determined by the Secretary of Agriculture to be commercial or industrial products (other than food or feed) that are composed in whole, or in significant part, of biological products or renewable domestic agricultural materials and forestry materials. Examples of USDA-designated biobased products include mobile equipment, hydraulic fluids, roof coatings, diesel

fuel additives, and towels. USDA is responsible for implementing the BioPreferredM procurement preference program. Information on these designated products, USDA's guidance, and related documentation can be found at USDA's web site at www.biopreferred.gov/. (The FAR is being revised to require that Federal agencies procure designated items composed of the highest percentage of biobased content practicable [FAR Case 2010-004].)

D. Environmentally Preferable Products and Services

Environmentally Preferable Products (EPP) are products or services that have a lesser or reduced effect on human health and the environment when compared with competing products or services that serve the same purpose. This comparison may consider raw materials acquisition, production, manufacturing, packaging, distribution, reuse, operation, maintenance, or disposal of the products or services. Examples of environmentally preferable products include cleaning products that are non-toxic, non-volatile, and biodegradable; and paint with no or low volatile organic compounds. This program is managed by EPA which maintains a database of products and specifications defined by federal, state, and local agencies, and other nations. The database can be found at www.epa.gov/epp along with EPA's Guidance on the Acquisition of Environmentally Preferable Products and Services located at <http://www.epa.gov/epp/pubs/index.htm>.

E. Electronic Product Environmental Assessment Tool (EPEAT) Products

EPEAT is a tool for evaluating the environmental performance of electronic products throughout their life cycle. EPEAT is intended to help purchasers in the public and private sectors evaluate, compare and select desktop computers, notebooks and monitors based on their environmental attributes. EPEAT also provides a clear and consistent set of performance criteria for the design of products, and provides an opportunity for manufacturers to secure market recognition for efforts to reduce the environmental impact of its products. Available at: <http://www.epeat.net/>

F. Water-Efficient Products

A water-efficient product is in the upper 25% of water efficiency for all similar products, or is at least 10% more efficient than the minimum level meeting U.S. Federal Government standards. Examples of products that have met the EPA WaterSense label include: high efficiency toilets, sink faucets, showerheads, urinals, and landscape irrigation systems. Information about the WaterSense Program is available at www.epa.gov/watersense.

G. Non-Ozone Depleting Substances

E.O. 13423 and the Council on Environmental Quality (CEQ) Implementing Instructions require that each agency give preference to the purchase of non-ozone depleting substances, as identified in EPA's Significant New Alternatives Policy (SNAP) program. FAR 23.803 states that agencies shall give preference to the procurement of alternative products that reduce overall risks to human health and the environment by lessening the depletion of ozone in the upper stratosphere. It further requires that in preparing specifications and purchase descriptions, and the acquisition of supplies and services, agencies shall comply with the requirements of the Clean Air Act and substitute safe alternatives to ozone-depleting substances.

SNAP provides lists of acceptable and unacceptable substitutes in the following sectors: fire suppressants, aerosol solvents and propellants, refrigeration and air conditioning equipments, and adhesives and coatings. SNAP is managed by EPA. Information about the SNAP Program is available on <http://www.epa.gov/ozone/strathome.html>

H. Alternative Fuel Vehicles and Alternative Fuels

Under EPAct, alternative fuel vehicles are defined as any dedicated, flexible-fuel, or dual-fuel vehicle designed to operate on at least one alternative fuel. As defined by EPAct, alternative fuels are substantially non-petroleum based fuels and include (but are not limited to) the following: ethanol at a 85% blend or higher (E85); liquefied petroleum gas (propane); compressed natural gas (CNG); biodiesel; electricity; hydrogen; and P-series fuels. DOE's FEMP manages this program. Information on these federal fleet requirements can be found at http://www1.eere.energy.gov/femp/about/fleet_requirements.html.

a. Sharing Research Data

[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. Data Other than Certified Cost or Pricing Data

- a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

3. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. Federal Acquisition Regulation Clauses incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

4. Other Administrative Data

a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

3. Government-Furnished Property

A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: http://rcb.cancer.gov/rcb-internet/reference/Appendix Q_HHS Contracting Guide.pdf

b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of Provision)

c. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d. Adequate Accounting System

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
 - Proper segregation of direct costs from indirect costs.
 - Identification and accumulation of direct costs by contract.
 - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
 - Accumulation of costs under general ledger control.

- A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
- A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
- Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
- Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
- Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
- Segregation of preproduction costs from production costs (applies primarily to manufacturing contracts).
- Provides financial information required by contract clauses concerning limitation of cost (FAR 52.232-20 and 21) or limitation on payments (FAR 52.216-16).
- Provides financial information required to support requests for progress payments.
- Ability to develop adequate reliable data for use in pricing follow-on acquisitions.
- Accounting system is in full operation."

e. Incremental Funding

An incrementally funded contract is a contract in which funds are obligated, as they become available, to cover specific periods of performance.

Incremental Funding, HHSAR 352.232-70 (June 2010)

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clauses at FAR 52.232-22, "Limitation of Funds," and 352.232-71, "Estimated Cost - Incrementally Funded Contract." The initial obligation of funds under the contract is expected to cover work assignment 1, for administrative activities for the base period . The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining years of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

f. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

Fac Cap Cost of Money (Has) The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

Fac Cap Cost of Money (Has Not) **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

5. Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. Performance History

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. Pertinent Contracts

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. Pertinent Grants

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and

past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

6. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

7. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

8. **Travel Costs/Travel Policy**

a. **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b. **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance, and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

2. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.

3. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. THE OFFEROR SHALL [INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL. / PROVIDE AN INDEX WITHIN ITS TECHNICAL PROPOSAL WHICH DIRECTS THE REVIEWER(S) TO THE SPECIFIC AREA(S) OF THE TECHNICAL PROPOSAL THAT ADDRESS A PARTICULAR MANDATORY QUALIFICATION.

The qualification criteria establishes conditions that must be met at the time of receipt of Final Proposal Revisions (FPRs) by the Contracting Officer in order for your proposal to be considered any further for award.

Mandatory Qualification Criteria

Listed below are mandatory qualification criteria. The offeror shall include all information which documents and/or supports the qualification criteria in a separate section of the Technical Proposal (see PART IV, Section L, Item 2.b., Technical Proposal Instructions). The qualification criteria establish conditions that must be met at the time of receipt of initial proposals by the Contracting Officer in order for the proposal to be considered for award.

A. All contractors shall be registered with the United States Food and Drug Administration (FDA) as a manufacturer of bulk drugs. The facilities shall meet FDA standards in accordance with the current Good Manufacturing Practices (cGMP) guidelines. The offeror shall show documented proof of the most recent routine FDA inspection(s). Moreover, the offeror must be in compliance with FDA requirements during the entire course of the contract period.

B. The facilities shall also conform to the applicable regulations of the U. S. Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), U. S. Department of Transportation (DOT) and those of state and local regulatory agencies. The proposal shall include documentation of registration for all minimum mandatory requirements.

4. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

5. TECHNICAL EVALUATION FACTORS

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are listed in order of relative importance.

EVALUATION FACTORS for AWARD

1. General

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost/price. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the Request For Proposal (RFP). The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. Technical Evaluation Criteria

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The four major technical evaluation criteria below are listed with weights assigned for evaluation purposes. Proposals submitted in response to this RFP will be evaluated in accordance with the following factors listed in descending order of relative importance:

a. PERSONNEL Weight 30 pts

(1) Suitability and adequacy of the Principal Investigator's (PI) training, recent hands-on experience in process/scale-up chemistry, scientific accomplishments, qualifications for leading this project, and availability for assignment. Since this work is predominantly scale-up and process development, publication records are less important than practical experience and demonstration of practical performance in large-scale chemical production. Communication between the Project Officer and the contractor is essential during the performance of projects and the PI will be a primary contact for technical discussions. The PI should be familiar with the FDA regulations/guidelines regarding GMP bulk production.

(2) Suitability and adequacy of the training, experience, qualifications, and scientific accomplishments of the entire proposed team members in the following areas:

- ? Synthetic organic or medicinal chemistry;
- ? Scale-up and process development of existing methods;
- ? Development of new and novel cost-effective processes;
- ? Large scale and/or pilot plant operations;
- ? Analytical chemistry including QA/QC functions;
- ? FDA regulations for GMP bulk production;
- ? Handling of potentially hazardous substances.

(3) Availability of the proposed team members, evidence and potential to perform as a team.

b. FACILITIES AND EQUIPMENT Weight 30 pts

Adequacy and availability of all the proposed facilities and equipment to perform the functions of this contract including:

a) Availability of large scale and/or pilot plant facilities, at least one (20-100 gallons) glass-lined reactor and several glass reaction vessels (50 and 100 L) with the necessary supporting equipment and laboratory space including multiple assignments need to be run in parallel.

b) Laboratory space and equipment for:

- ? Organic/Medicinal Chemistry Synthesis;

? Purification and structure determination of intermediates and target material;

? Analytical-Quality Control to comply with QA/QC requirements;

? Library and/or other comparable information facilities (e.g. computing, software and electronic information);

? Unique and "back-up" equipment(s); and

? Special facilities for the handling of hazardous and toxic reactions and disposal of waste.

c. UNDERSTANDING of PROBLEM and TECHNICAL APPROACH Weight 30 pts

Recent three to four large scale (100 gm to multi-kilogram, at least five or more step synthesis) GMP bulk drug preparations should be described in detail as part of previous experiences of the PI and the proposed team. Within that description the following points should be included and discussed as much as possible:

? Demonstrated understanding of the requirements of the Statement of Work

? Potential problems/concerns and resolution approach during yield optimization/process development and scale up;

? Understanding of the approach to the scale up syntheses of bulk chemicals for which only a literature information is available but it is not practical for large scale;

? Issues on FDA regulatory concerns;

? Efforts on acquiring starting material or advanced intermediates from various vendors in terms of effectiveness of timeline and cost;

? Issues on estimated timeline and cost of project and actual outcome;

? Handling of toxic materials and approach to handle toxic materials; and

? Names of team members and their roles including role of the proposed PI in the provided examples.

d. ORGANIZATIONAL SUPPORT and EXPERIENCE Weight 10 pts

(1) Demonstrated organizational experience in process development, scale-up of synthetic organic/medicinal compounds, and QA/QC

(2) Organization's ability to provide appropriate personnel and resources for the project and to give priority to the NCI project

(3) Relevance of examples cited to support the organization? s ability to manage and operate synthesis laboratories and production facilities.

(4) Ability of the organization to handle varying levels of assigned work, including simultaneous projects or periods with no active projects.

(5) Adequacy of the safety and security procedures to be used in conducting the proposed work.

(6) Adequacy of the responses to 352.223-71 "Instruction to Offerors - Sustainable Acquisition".

TOTAL 100 pts

e. PAST PERFORMANCE INFORMATION

(1) Offeror's past performance will be evaluated after determination of the competitive range. Only those offerors included in the competitive range will be evaluated. The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror.

(2) The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's records of past performance.

(3) The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

(4) When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

(5) The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

(6) The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

f. SUSTAINABLE ACQUISITION PLAN

The Offeror's proposal must demonstrate compliance with FAR 23.1, "Sustainable Acquisition Policy" and the interim rule entitled "Sustainable Acquisition" at <http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-12851.pdf> (FAR case 2010-001, FAC 2005-52). Due to the late addition of this requirement in the subject Request for Proposals, if the proposal does not include a Sustainable Acquisition Plan that addresses the environmental products and services to be utilized under the resulting contract, or if the Plan is considered to be "poor" and the Government includes your proposal in the competitive range, the Offeror will be afforded the opportunity to further discuss, clarify, or modify the Plan during discussions and in their Final Proposal Revision (FPR). The Government is seeking to determine whether the Offeror has demonstrated a commitment to advance sustainable products and services.

The following evaluation criterion will be used in review of the Sustainable Acquisition Plan:

Descriptor Proposal qualities

Excellent:

Documents compliance with relevant environmental laws and regulations to acquire supplies and services that promote energy and water efficiency, advance the use of renewable energy products, and help foster markets for emerging technologies. Implements cost- effective contracting preference programs promoting energy- efficiency, water conservation and the acquisition of environmentally preferable products and services (e.g., computer monitor, desktop computer, notebook computer and personal computer products. Minimizes the procurement of materials and substances that contribute to the depletion of stratospheric ozone. Gives preference to the procurement of alternative chemical, product, and manufacturing processes that reduce overall risks to human health and the environment by lessening the depletion of ozone in the upper atmosphere. Reduces paper use and acquires paper containing at least 30% postconsumer fiber.

Good:

Documents compliance with relevant environmental laws and regulations and commits the organization to more aggressive actions such as: Develops and implements innovative policies and practices to reduce scope 3 GHG emissions in HHS operations. Manages existing buildings to reduce energy, water, and materials consumption. Implements and achieves objectives in EPA's Storm water Management Guidance. Reduces paper use and acquires paper containing at least 30% postconsumer fiber. Minimizes the acquisition, use, and disposal of toxic and hazardous materials. Employs environmentally sound practices for the disposition of all agency excess or surplus electronic products. Procures Energy Star and FEMP-designated electronic equipment. Continues implementation of existing Environmental Management System (EMS) programs.

Fair:

Documents existing programs that meet relevant environmental laws and regulations and proposes modest further steps.

Poor:

Merely states that the offeror will comply with relevant environmental laws and regulations, or describes programs that merely comply with relevant laws.

6. Sustainable Acquisition Plan

6. The Offeror's proposal must demonstrate compliance with FAR 23.1, "Sustainable Acquisition Policy" and the interim rule entitled "Sustainable Acquisition" at <http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-12851.pdf> (FAR case 2010-001, FAC 2005-52). Due to the late addition of this requirement in the subject Request for Proposals, if the proposal does not include a Sustainable Acquisition Plan that addresses the environmental products and services to be utilized under the resulting contract, or if the Plan is considered to be "poor" and the Government includes your proposal in the competitive range, the Offeror will be afforded the opportunity to further discuss, clarify, or modify the Plan during discussions and in their Final Proposal Revision (FPR). The Government is seeking to determine whether the Offeror has demonstrated a commitment to advance sustainable products and services.

7. PAST PERFORMANCE FACTOR

Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.